

This document was submitted to EPA by a registrant in connection with EPA's evaluation of this chemical, and it is presented here exactly as submitted.



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HAND DELIVERED

September 30, 1994

Mr. Peter Caulkins
Deputy Director
Special Review and Reregistration Division
U.S. Environmental Protection Agency
2800 Crystal Drive (Crystal Station 1)
Arlington, VA 22203

Re: Settlement Agreement - Oxydemeton-methyl

Dear Mr. Caulkins:

Enclosed is EPA's copy of the original signed settlement agreement between Gowan Company and the Agency concerning the reregistration of products containing oxydemeton-methyl as the active ingredient. A second signed original is retained at Gowan Company.

With the Agreement finalized, we request that EPA complete the registrations transfer and approval of amended labeling, as specified in the Agreement, as expeditiously as possible so that Gowan may begin marketing product.

We appreciate your assistance in bringing closure to the negotiations between Gowan Company and the Agency.

Sincerely,

A handwritten signature in cursive script, appearing to read "Elizabeth Codrea".

Elizabeth Codrea
Regulatory Product Manager



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Settlement Agreement

The Gowan Company (Gowan) and the Environmental Protection Agency (EPA) have reached the following agreement concerning the generation of data to support the reregistration of pesticide products containing oxydemeton-methyl (ODM) as the active ingredient. This written agreement constitutes the entire agreement between Gowan Company and the Environmental Protection Agency.

Background

In EPA's 1987 Registration Standard, September 1992 Data Call-In, and April 1993 Data Call-In, EPA required all registrants of products containing the active ingredient oxydemeton-methyl to submit certain data to support the reregistration of oxydemeton-methyl and to continue registration of their products. The technical registrant, Miles Inc. committed to conduct the studies necessary to maintain its registrations. On June 30, 1994 Miles Inc. submitted an application to transfer all its oxydemeton-methyl products to Gowan Company.

At the time Miles Inc. requested voluntary cancellation of its ODM products, the due dates for various data required to support ODM reregistration were approaching. The due dates have since lapsed. The data have not been submitted and are currently overdue. As a result, pursuant to FIFRA sections 3(c)(2)(B), EPA has the basis to issue a Notice of Intent to Suspend against all products containing oxydemeton-methyl.

Agreement

By entering into this agreement, Gowan Company hereby agrees that its pending oxydemeton-methyl registrations are governed by the terms and conditions of this agreement. EPA is prepared to grant Gowan extensions for submission of the data required to support reregistration of oxydemeton-methyl products, as identified in Appendix A, if Gowan submits to EPA labeling bearing amendments required by this agreement no later than one week from EPA's approval of the transfer of Miles' ODM products to Gowan. EPA will endeavor to review the amendments and issue an approval or denial within 30 days.

The oxydemeton-methyl registrations 3125-111 and 3125-99 are subject to the following terms and conditions:



Recycled/Recyclable
Printed with Soy/Canola Ink on paper that
contains at least 50% recycled fiber

- (A) The oxydemeton-methyl product formerly 3125-111 released for shipment on or after the date of this agreement must bear the label amendments required in this agreement [i.e. Section (B), (C), (D), (E), and (G).]
- B) (i) The following spray drift label language will be required on all of Gowan's oxydemeton-methyl products:

SPRAY DRIFT MANAGEMENT

AVOIDING SPRAY DRIFT IS THE RESPONSIBILITY OF THE APPLICATOR. The interaction of many equipment-and-weather-related factors determine the potential for spray drift. The applicator is responsible for considering all these factors when making decisions.

The following spray drift management requirements must be followed to avoid off-target movement from aerial applications:

1. Do not apply within 150 feet by air or 100 feet by ground of an unprotected person or occupied building.
 2. All application equipment must be properly maintained and calibrated using appropriate carriers.
 3. The spray boom should be mounted on the aircraft so as to minimize drift caused by wing tip vortices. The boom length must not exceed 3/4 of the wing or rotor length (i.e. the distance of the outermost nozzles on the boom must not exceed 3/4 the length of the wingspan or rotor.)
 4. Nozzles must always point backward and never be pointed downwards more than 45 degrees.
 5. Do not apply at a height greater than 10 feet above the crop canopy unless a greater height is required for aircraft safety.
 6. Make applications when wind velocity favors on-target product deposition (approximately 3 to 10 mph). Do not apply when gusts or sustained winds exceed 15 mph.
- (ii) These requirements will be reevaluated by EPA following completion of an ODM risk assessment.

- C) The following amendments to the directions for use will be incorporated on Gowan's oxydemeton-methyl products:

Commodity**Restriction**

- cucumber A three day Pre Harvest Interval (PHI)
- peppers A three day PHI
- summer squash A three day PHI
- christmas trees A maximum of 2 applications per season
- nursery stocks A maximum of 2 applications per season
- sugarbeets A maximum of 2 applications per season
- alfalfa seed A maximum of 2 applications per season
- clover seed A maximum of 2 applications per season
- walnut A maximum of 1 application per season and 400 gallons of finished spray solution per acre; and a 30 day PHI
- nonbearing fruits A maximum of 3 applications per season and 300 gallons of finished spray solution per acre per application

- D) Gowan agrees not to market ODM on the crops listed in Table 1 with the exception that Gowan may market ODM on citrus if EPA approves (a) FIFRA Section 18 registration(s) for this use. These uses may be retained on all ODM technical and end-use registrations on file with the Agency as the most current approved labels and tolerances will remain in place. Gowan may request to reinstate these uses on marketing labels after EPA's favorable review of the necessary data and EPA's completion of the oxydemeton-methyl dietary and worker risk assessments at the time of the oxydemeton-methyl Reregistration Eligibility Decision.

Table 1 <i>Uses to be deleted from Gowan's oxydemeton-methyl marketing labels</i>	
corn, field	onions
popcorn	pears
sorghum	turnips
safflower	snapbeans
citrus	

(E) Gowan agrees to place a restriction on its labels requiring closed mixing and loading systems for both aerial and chemigation application methods and agrees to implement a plan to communicate the changes and to phase-in the use of closed mixing and loading systems for application methods other than air application and chemigation. EPA agrees to Gowan's gradual implementation of closed mixing and loading systems for the other application methods in three phases as outlined below. Elements of this plan will include but are not limited to:

- (i) Phase 1. Closed systems for handling and mixing ODM for aerial applications and chemigation systems are required. Gowan will hold meetings and communicate this new label change with users, applicators, growers, etc..
- (ii) Phase 2. Within twelve months of the signature date of this agreement, Gowan will identify the larger users of ODM through ground application, such as certain custom applicators, and use financial or other marketing incentives to secure their cooperation and utilization of the closed systems, provide training programs on closed systems to explain and encourage their use, and provide literature on the use of closed mixing and loading systems to users via a direct-mail campaign.
- (iii) Phase 3. Within twenty-four months of the signature date of this agreement, Gowan will identify intermediate to smaller users and use financial or other marketing incentives to secure their cooperation and utilization of the closed systems and provide training programs and literature on closed systems to explain and encourage their use.
- (iv) By December 31, 1994 Gowan will submit to the Reregistration Branch, Special Review and Reregistration Division its detailed written program to implement a phase-in program for closed mixing and loading systems incorporating the elements and timeframes identified in paragraphs (E)(i)-(iii). Progress reports will be submitted to the Reregistration Branch, Special Review and Reregistration Division every six months thereafter.

The requirement for closed mixing systems will be reevaluated by EPA following completion of an ODM risk assessment.

(F) Gowan will cancel WA-800069 for Douglas Fir Trees within 30 days of the signature date of this agreement and will include a request to waive the 90-day period under section 6(f)(1)(c)(ii).

- (G) Gowan will translate all Worker Protection Standard language as approved by EPA on April 18, 1994 for Metasystox-R (3125-111) into Spanish on the label.
- (H) As an alternative to closed mixing and loading systems, Gowan agrees to examine the technical feasibility of converting ODM end-use products to be used in water soluble packaging and to report to the Agency annually on progress.
- (I) Gowan commits to generating the data required by reregistration by the due dates identified in Appendix A.
- (J) Gowan commits to providing progress reports describing the current status of its efforts to generate and submit the required data, all the steps it has taken to meet the requirements since Gowan last provided the Agency with written information on such study, and its future plans and timetable to meet each requirement by the deadlines noted in Appendix A. The initial status report was submitted on September 8, 1994 and will be supplemented quarterly until the last of the studies is submitted (i.e. December 8, 1994, March 8, 1995, June 8, 1995, September 8, 1995, December 8, 1995, March 8, 1996, June 8, 1996, September 8, 1996, December 8, 1996.)
- (K) Gowan agrees that EPA may by an order and without opportunity for hearing suspend Gowan's oxydemeton-methyl products
 - (i) if Gowan does not deliver the progress reports or acceptable data by the dates specified in items E and J and in the Appendix A; or
 - (ii) if Gowan submits a progress report that demonstrates Gowan is not taking the necessary steps to generate and submit the required data acceptable to the Agency on the specified schedule, or if the submitted progress report indicates that Gowan cannot submit the required data within the specified timeframes, or that the required written program to implement a phase-in program for closed mixing and loading systems (or the progress reports for that program) demonstrates that Gowan is not making a good faith effort to comply with provision E.
 - (iii) if the Agency concludes on the basis of other information that Gowan is not taking steps necessary to submit acceptable data according to schedule or making a good faith effort to comply with other terms of this agreement.

Gowan will have the right and reasonable opportunity to respond to EPA reviews of the progress reports or data specified in items E and J and in Appendix A with information to upgrade the progress reports or data to acceptable status if necessary.

Gowan will have the right and reasonable opportunity to respond to any information as specified in item K (iii) to demonstrate that a good faith effort is being made to comply with the terms of this agreement.

Before EPA suspends any oxydemeton-methyl registration for failure to meet a deadline established under this agreement, Gowan shall have the right and reasonable opportunity to appear before the Office of Pesticides Program's Division Director for Special Review and Reregistration to explain and document the events responsible for the delay.

EPA may grant further extension to the deadlines for data submission if the failure to meet the agreed upon deadlines results from acts of God or *force majeure*.

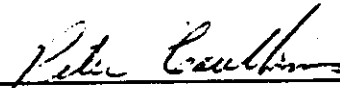
Gowan understands and agrees that sale or distribution of oxydemeton-methyl products after receipt of an Agency notification that the products have been suspended is an unlawful act under FIFRA section 12.

Gowan agrees to waive any rights to challenge in any forum suspension of its oxydemeton-methyl products effectuated pursuant to the agreement, except as specified in item K.


EPA understands that it has the discretionary authority to extend the dates for submission of the required data. However, Gowan agrees that any decision to suspend the oxydemeton-methyl registrations due to failure to submit the required data is discretionary and unreviewable in any forum, except as specified in item K.

- (L) Gowan understands that ODM is a chemical that is still in Special Review. Additionally, nothing in this agreement prohibits the Agency from taking other regulatory actions on the registration of ODM, and/or requiring the submission of additional data to support the registration of products containing ODM.

Gowan's failure to comply with any of the terms or conditions of this agreement shall constitute a breach of the agreement, and the extension for data submission shall be withdrawn. Gowan's failure to comply with any of the terms or conditions of the agreement shall also constitute a violation of the terms or conditions of registration, and the products shall be subject to cancellation pursuant to Section 6(e) of FIFRA.



Louis P. True, Jr. Acting Director
Special Review and
Reregistration Division

 9/30/94

Authorized Representative
Gowan Company
IAN WATKINSON PH.D.
VICE PRESIDENT.

OXYDEMETON-METHYL OUTSTANDING REREGISTRATION DATA REQUIREMENTS			
GDLN #	GUIDELINE NAME	DUE DATE	COMMENT
61-2a	beginning materials and manufacturing process		data are in review
61-2b	discussion of impurities		data are in review
62-1	preliminary analysis		data are in review
62-2	certification of limits		data are in review
62-3	analytical methods		data are in review
63-6	boiling point		data are in review
63-7	density		data are in review
63-9	vapor pressure		data are in review
63-10	dissociation constant		data are in review
63-12	pH		data are in review
	product chemistry data requirements for the manufacturing use product		data are in review
71-4a	avian reproduction - quail		data are in review
71-4b	avian reproduction - duck		data are in review
72-4a	early life stage - fish		data are in review
72-4b	life cycle - invertebrate		data are in review
81-8	acute neurotoxicity - rat	1 year from EPA review of protocol	
82-6 (82-5a)	90-day neurotoxicity - hen (additional material required to upgrade the study)		data are in review
82-7 (82-5b)	90-day neurotoxicity - mammal	2 years from EPA review of protocol	

OXYDEMETON-METHYL OUTSTANDING REREGISTRATION DATA REQUIREMENTS			
GDLN #	GUIDELINE NAME	DUE DATE	COMMENT
83-1a	chronic toxicity - rat (90-day dietary study demonstrating brain cholinesterase inhibition)	9/30/95	
83-1b	chronic toxicity - non-rodent (additional material required to upgrade the study)		data are in review
83-2b	oncogenicity - mouse		data are in review
83-3b	teratogenicity - rabbit	9/30/95	
132-1a	foliar residue dissipation	<ul style="list-style-type: none"> ● Protocol due within 90 days of receipt of DCI ● Study due within 24 months of receipt of DCI 	
132-1b	soil residue dissipation	<ul style="list-style-type: none"> ● Protocol due within 90 days of receipt of DCI ● Study due within 24 months of receipt of DCI 	
133-3	dermal passive dosimetry exposure	<ul style="list-style-type: none"> ● Protocol due within 90 days of receipt of DCI ● Study due within 24 months of receipt of DCI 	
161-3	photodegradation - soil		data are in review
162-1	aerobic soil metabolism		data are in review
162-3	anaerobic aquatic metabolism		data are in review
163-1	leaching/adsorption/desorption		data are in review

OXYDEMETON-METHYL OUTSTANDING REREGISTRATION DATA REQUIREMENTS			
GDLN #	GUIDELINE NAME	DUE DATE	COMMENT
164-1	terrestrial field dissipation - additional data may be required pending review of metabolism data		
165-1	confined rotational crop	9/30/96	
171-4a	nature of the residue - plant	6/30/96	
171-4b	nature of the residue - animal	6/30/96	
171-4c	storage stability	2/97	
171-4k	magnitude of the residues in plants	6/30/96	
171-4l	magnitude of the residues in processed commodities	6/30/96	